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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,322	07/02/2001	David M. Valenzuela	REG 132-B1	3509

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	6

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,322	VALENZUELA ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-36* is/are pending in the application.

4a) Of the above claim(s) *31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The response to the restriction requirement, filed October 23, 2002, is acknowledged.

Group V, consisting of claims 35 and 36, was elected, without traverse.

Claims 31-36 are pending. Claims 31-34, drawn to non-elected inventions, are withdrawn from consideration.

Claims 35 and 36 are examined on the merits.

Claim Rejections - 35 USC § 112

2. Claims 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 35 and 36 are drawn to methods for treatment of human or animal, comprising administering a therapeutic dosage of noggin polypeptide, having the amino acid sequence set forth as SEQ ID NO: 2. The specification teaches that SEQ ID NO: 2 is human noggin. The treatment may be regulation of cartilage and bone growth, therapy of a congenital condition or degenerative disorder of the nervous system, and treatment of damaged nerve cells.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence

or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See Ex parte Forman, 230 USPQ 546, BPAI, 1986.

The specification discloses naturally occurring noggin polypeptides from frog, mouse and human. The amino acid sequence of the human polypeptide is set forth as SEQ ID NO: 2. The polypeptides have activity in a disclosed dorsalizing assay, wherein the addition of noggin rescues a complete dorsal-ventral axis in Xenopus embryos at the four-cell stage. Also, the naturally occurring noggin polypeptides induced expression of neural development markers including NCAM and XIF3 in animal caps from the blastula to mid-gastrula stages without inducing mesoderm development markers such as muscle actin, goosecoid, and X-bra. This evidence is not predictive of the effects noggin may have on the claimed cartilage/bone regulation, congenital/degenerative nerve tissue, or damaged nerves for several reasons. First there is no evidence that the disclosed noggin proteins have any activity on cartilage or bone tissue. The systems in which the noggin proteins were tested are not model systems for cartilage or bone. Therefore, a protein's activity in these systems would not be predictive of the activity in cartilage or bone. Second, the embryonic animal cap system is not predictive of adult nerve tissue. The embryonic neural system is growing and developing; the adult neural system is matured and differentiated. The effect a protein has on embryonic tissue cannot be predictive of the effect it will have on aged, degenerated nerve tissue, such as is the case in Alzheimer's disease. See Pepeu et al. Also, damaged nerve tissue, such as severed nerve tissue, quickly degenerates and dies. A protein's effect on growing embryonic nerve tissue cannot be predictive of its effect on degenerative, damaged, possibly dead, nerve tissue. Also, the claims encompass

treatment of the central nervous system, which is well known in the art to be recalcitrant to treatment. See Jackowski et al. Therefore, due to the large quantity of experimentation necessary to extend the embryonic system to adult systems; the lack of direction or guidance presented specific for adult systems; the absence of working examples for adult systems, damaged nerve systems, congenital/degenerative nerve disorder systems, and cartilage/bone systems; the complex nature of the inventions; the state of the prior art which shows the recalcitrance of adult nervous systems to treatment; the unpredictability of the art; undue experimentation would be required of the skilled artisan to make and use the claimed methods of treatment.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
January 13, 2003

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